REMARKS

With the addition of claims 36-47, claims 1-49 are pending.

The amendments to claims 1 and 26 are supported by the specification at page 5, lines 8-10 and 16-18, which discloses that "high purity torsemide modification II" has no trace amounts of modification I and "trace amounts" are defined as about 0.5 to about 2 weight%. The amendments to claims 18- 32, as well as the addition of claims 36-49, are supported by the specification at page 4, lines 15-21; page 5, lines 9- 27; page 6, lines 1-8; page 7, lines 5-6 and 25-28, and page 8, lines 1-4. The replacement of "crystal" with "crystals" in claims 20 and 30 is cosmetic and supported by the specification at page 4, lines 25-26. No new matter has been introduced by the claim amendment.

The replacement of "which does not substantially rearrange" with "wherein no more than 15% of the torsemide modification II rearranges" in claims 18 and 28 should not narrow the scope of the amended claim recitation because "substantial rearrangement" is defined in page 5, lines 18-20, of the specification to mean any rearrangement of more than about 15% of one polymorphic form into any other polymorphic form of torsemide, e.g. modification I.

Information Disclosure Statement

Applicants request that the Examiner return a copy of the PTO-1449 Form filed as a part of an IDS on May 28, 2002 with his initials to acknowledge consideration of the prior art references cited therein.

Obviousness-Type Double Patenting

Applicants respectfully traverse the rejection of claims 16-35 over the claims of U.S. Patent No. 6,482,417 (US '417) under the doctrine of obviousness-type double patenting. Applicants disagree that claims 16-35 are not patentably distinct from the claims of US '417. Claims 16-35 are patentably distinct from the claims of US '417 because, in making the Restriction Requirement final, the Office Action already holds that claims 16-35 are patentably distinct from claims 6-15. Claims 6-15 are substantially similar to claims 1-13 of US '417. Claims 6-15 are drawn to a stable pharmaceutical composition comprising torsemide modification II that does not substantially rearrange into another polymorphic form, e.g. modification I, over time upon storage. Claims 1-13 of US '417 are also drawn to a stable pharmaceutical composition comprising high purity torsemide modification II that does not substantially rearrange into modification I. If claims 16-35 are patentably distinct

from claims 6-15, it naturally follows that claims 16-35 are patentably distinct from the claims of US '417. Applicants submit that the Restriction Requirement and the obviousness-type double patenting rejection conflict with each other. Withdrawal of the Restriction Requirement or the obviousness-type double patenting rejection is requested.

Claim Rejections -- 35 U.S.C. 112, Second Paragraph

Applicants respectfully traverse the indefiniteness rejections of claims 1 and 16-35 over the phrases, "high purity" and "does not substantially change over time." The phrase "does not substantially change over time" is not found in the claims. Applicants assume that the Examiner meant "does not substantially rearrange over time." Applicant disagree that "does not substantially rearrange" is indefinite because of the definition of "substantial rearrangement" in page 5, lines 18-20, of the specification. With the deletion of "high purity" and "over time", withdrawal of the indefiniteness rejections is requested.

Claim Rejection -- 35 U.S.C. 102

A. Applicants respectfully traverse the anticipatory rejection of claims 16-22 and 26-32 over Aronhime et al (US 6,465,496).

The Examiner based the rejection on torsemide Dupont Form 2 disclosed in Aronhime et al (see Example 2). However, torsemide Dupont Form 2 is not the same as torsemide modification II (see page 85, right column, lines 7-9, Rollinger et al, *Eur. J. Pharmaceutics Biopharmaceutics*, 53 (2002) 75-86, cited in the IDS filed on July 23, 2003). Thus, there was no anticipation based on the disclosure of torsemide Dupont Form 2 in Aronhime et al.

B. Applicants respectfully traverse the anticipatory rejection of claims 16-18, 20-28 and 30-35 over Dreckmann-Behrendt (US 5,914,336). The rejection was based on the tablet disclosed in Example 5 of Dreckmann-Behrendt. However, the tablet contained 10 wt% modification II, 45 wt% modification I and 45 wt% modification III. Due to the high level of modification I in the tablet, Dreckmann-Behrendt fails to anticipate claims 16-18, 20-28 and 30-35, which require modification II containing modification I at less than about 0.5 wt%.

Claim Rejection – 35 U.S.C. 103

Applicants respectfully traverse the obviousness rejection of claim 1 over Aronhime et al in view of Crenshaw et al (US 4,380,638). The Examiner relied on the disclosures of Aronhime et al of a process of preparing torsemide Dupont Form 2 and a process of preparing

modification II starting with amorphous torsemide. Crenshaw et al was relied upon for the teaching of equivalence between ethanol and acetonitrile.

This obviousness rejection uses Aronhime et al as prior art via 35 U.S.C. 102(e). However, Aronhime et al and the instant application were both assigned to Teva Pharmaceutical Industries, Ltd.

Statement of Common Ownership

Applicants hereby state that the instant application and Aronhime et al were at the time the invention of the instant application was made, owned by, or subject to an obligation of assignment to, Teva Pharmaceutical Industries, Ltd.

With common ownership, Aronhime et al is not proper prior art according to 35 U.S.C. 103(c). Withdrawal of the obviousness rejection is requested.

Conclusion

In view of the above reasoning, applicants submit that the application is in a condition for allowance. If anything can be done to expedite the prosecution, the Examiner is invited to call the undersigned to discuss it.

If the filing of this paper is deemed not timely, applicants petition for an appropriate extension of time. The petition fee, and any other fees that may be required in relation to this paper, can be charged to Deposit Account 11-0600, referencing Docket No. 01662/51303.

Respectfully submitted,
KENYON & KENYON

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By: King L. Wong
King L. Wong, Ph.D.
Reg. No. 37,500

1500 K Street, N.W., #700
Washington, DC 20005-1257
Tel.: (202) 220-4200
Fax: (202) 220-4201

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